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Bass measure will benefit patients with rare diseases

May 30, 2012

WASHINGTON – Legislation sponsored by Congressman Charles F. Bass (NH-02) was included in a bipartisan legislative package that passed the House this evening. The Bass bill, H.R. 3211, the Humanitarian Device Reform Act, would make it easier for medical device manufacturers to create and produce devices for individuals with rare diseases.

Bass' measure was included in H.R. 5651, the Food and Drug Administration Reform Act, a bill that reauthorizes current user fee programs for prescription drugs and medical devices, establishes user fee programs for generic drugs, and reforms certain Food and Drug Administration (FDA) programs. The bill passed by an overwhelming majority of 387 to 5.

Bass said:

"This legislation is a great example of Congress coming together to find bipartisan solutions to ensure drug safety and spur medical advancements.

"I'm especially pleased that my legislation was included in the final language. After working with New Hampshire businesses and stakeholders, I crafted my bill to ensure that medical device manufacturers have fewer barriers to be able to develop products that will help ease the suffering for many patients with rare diseases.

"In this fragile economic recovery, the last thing we should do is make it harder for job creators to expand and create new jobs. This legislation will spur innovations in the health care industry while at the same time improving regulations to increase transparency and market involvement. I hope the House and Senate can work out the differences between their two bills as soon as possible so the President can sign it into law right away."

Specifically, Bass' measure (H.R. 3211), which was included in the overall FDA user fee bill passed by the House today, would repeal the outdated profit cap on Humanitarian Use Devices (HUDs), which are innovative medical devices used to treat rare diseases. The "no-profit" cap on the sale of these devices discourages manufacturers, particularly smaller companies, from pursuing new developments in the industry, growing their businesses, and creating new jobs. While the no-profit cap was lifted for pediatric devices five years ago, it has not been lifted for adult devices.

Bass' legislation is supported by the National Organization for Rare Disorders, [which stated](#) Bass' bill will ensure "that all Americans, both children and adults, have access to life-saving medical devices treating or diagnosing rare conditions."

Next month, the House is expected to consider legislation to repeal the 2.3 percent tax on medical devices that was included in the new health care law. The tax has severely impacted

medical device manufacturers' ability to invest in their companies and spur innovation in the industry. Bass is a cosponsor of the Protect Medical Innovation Act (H.R. 436), which would repeal this unfair and burdensome tax.

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